ISO 11140-6:2022-11 (E)

Sterilization of health care products - Chemical indicators - Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 2

3 Termsanddefinitions 2

4 Requirements 3
4.1 General 3
4.2 Porous devices 3
4.2.1 Reference porous device (RPD) 3
4.2.2 Detector for reference porous device (RPD) 4
4.2.3 Alternative porous indicator system (APIS) 5
4.2.4 Reference porous device (RPD) response 6
4.3 Hollow devices 6
4.3.1 Reference hollow device (RHD) 6
4.3.2 Detector for reference hollow device (RHD) 7
4.3.3 Reference hollow indicator system (RHIS) 8
4.3.4 Reference hollow indicator system (RHIS) performance determination 8
4.3.5 Leakage test 9
4.4 Alternative hollow indicator system (AHIS) 9
4.4.1 General 9
4.5 Alternative hollow devices intended for multiple use 10
4.6 Test procedure for validation of conformance of the alternative hollow device to the reference hollow device (RHD) 12

5 Chemical indicator dry heat performance 13
5.1 General 13
5.2 Test 1 13
5.3 Test 2 14

6 Marking and labelling 14
6.1 Device labelling 14
6.2 Additional labelling requirements for hollow devices 14
6.3 Chemical indicators for use in hollow devices 15

Annex A (normative) Test method for performance of reference hollow indicator system (RHIS) 16

Annex B (normative) Test method for performance of alternative porous indicator system (APIS) 24

Annex C (normative) Test method for performance of alternative hollow indicator system (AHIS) 27

Annex D (informative) Relationship between chemical indicator components 28

Annex E (normative) Reference hollow device (RHD) 30

Annex F (informative) Accelerated ageing of test samples 32

Annex G (informative) Evaluation of reference hollow devices (RHDs) -- Interlaboratory results 33

Bibliography 40